



Drug Enforcement Administration

[Docket No. DEA-982]

Bulk Manufacturer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen Pharmaceuticals Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: DEA requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.”

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 10, 2021, Janssen Pharmaceuticals Inc., 1440 Olympic Drive Athens, Georgia 30601-1645, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Methylphenidate	1724	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Oripavine	9330	II
Thebaine	9333	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. No other activities for these drug codes are authorized for this registration.

Matthew J. Strait,
Deputy Assistant Administrator.